

initial disclosures pursuant to Paragraph 3 of the D. Del. Default Standard within 30 days of the Rule 16 Conference.

2. Joinder of Other Parties and Amendment of Pleadings.

a. All motions to join other parties shall be filed on or before January 28, 2019.

b. All motions to amend or supplement the pleadings shall be filed on or before July 30, 2019.

3. Application to Court for Protective Order. Counsel will confer and attempt to reach an agreement on a proposed form of a protective order specifying terms and conditions for the disclosure of confidential information and submit it to the Court by July 27, 2018. Should counsel be unable to reach an agreement on a proposed form of order, counsel must follow the provisions of Paragraph 7(k) below.

Any proposed protective order must include the following paragraph:

Other Proceedings. By entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a motion to disclose another party's information designated "confidential" [the parties should list any other level of designation, such as "highly confidential," which may be provided for in the protective order] pursuant to this order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

4. Papers Filed Under Seal. In accordance with section G of the Administrative Procedures Governing Filing and Service by Electronic Means, a redacted version of any sealed document shall be filed electronically within seven (7) days of the filing of the sealed document. Should any party intend to request to seal or redact all or any portion of a transcript of a court proceeding (including a teleconference), such party should expressly note that intent at the start

of the court proceeding. Should the party subsequently choose to make a request for sealing or redaction, it must, promptly after the completion of the transcript, file with the Court a motion for sealing/redaction, and include as attachments (i) a copy of the complete transcript highlighted so the Court can easily identify and read the text proposed to be sealed/redacted, and (ii) a copy of the proposed redacted/sealed transcript. With their request, the party seeking redactions must demonstrate why there is good cause for the redactions and why disclosure of the redacted material would work a clearly defined and serious injury to the party seeking redaction.

5. Courtesy Copies. Other than with respect to “discovery matters,” which are governed by paragraph 7(k), and the final pretrial order, which is governed by paragraph 18, the parties shall provide to the Court two (2) courtesy copies of all briefs and one (1) courtesy copy of any other document filed in support of any briefs (i.e., appendices, exhibits, declarations, affidavits etc.). This provision also applies to papers filed under seal.

6. ADR Process. This matter is referred to a magistrate judge to explore the possibility of alternative dispute resolution.

7. Discovery. Unless otherwise ordered by the Court, the limitations on discovery set forth in Local Rule 26.1 shall be strictly observed.

a. Identification of Accused Products and Asserted Patents. By July 16, 2018, Plaintiff shall identify the accused products and the asserted patents they allege are infringed and produce the file history for each asserted patent, pursuant to Paragraph 4(a) of the D. Del. Default Standard.

b. Production of Core Technical Documents. By August 16, 2018, Defendant shall produce to Plaintiff its core technical documents, including, Abbreviated New Drug Application (“ANDA”) No. 209431 and any amendments or supplements thereto, along with any

and all related correspondence to/from the FDA related to said ANDA; and Plaintiff shall produce to Defendant its core technical documents, including, New Drug Application (“NDA”) No. 208090 and any amendments or supplements thereto, along with any and all related correspondence to/from the FDA related to said NDA.

c. Plaintiff’s Claim Chart. By October 8, 2018, Plaintiff shall provide to Defendant an initial claim chart relating each accused product to the asserted claims each product allegedly infringes, pursuant to D. Del. Default Standard Paragraph 4(c).

d. Defendant’s Initial Invalidity Contentions. By December 3, 2018, Defendant shall produce to Plaintiff its initial invalidity contentions for each asserted claim, as well as the related invalidating references (e.g., publications, manuals, and patents), pursuant to D. Del. Default Standard Paragraph 4(d).

e. Discovery Cut Off. All discovery in this case shall be initiated so that it will be completed on or before July 30, 2019.

f. Document Production. Document production shall be substantially complete by March 11, 2019.

g. Requests for Admission. A maximum of 50 requests for admission are permitted for each side. These limitations do not apply to requests for admission directed to authenticity or admissibility of documents. The parties will work to agree on authentication to the extent possible.

h. Interrogatories.

i. A maximum of 25 interrogatories, including contention interrogatories, are permitted for each side.

ii. The Court encourages the parties to serve and respond to contention interrogatories early in the case. In the absence of agreement among the parties, contention interrogatories, if filed, shall first be addressed by the party with the burden of proof. The adequacy of all interrogatory answers shall be judged by the level of detail each party provides; i.e., the more detail a party provides, the more detail a party shall receive.

i. Depositions.

i. Limitation on Hours for Deposition Discovery. Each side is limited to forty (40) hours of taking fact testimony by deposition upon oral examination, not including inventors. This limitation includes 30(b)(6) time but does not apply to expert witnesses and third-party fact depositions, except that any fact depositions of Plaintiff's or Defendant's former employees represented by Plaintiff's or Defendant's counsel respectively shall be included in the hour limit of the party taking the deposition.

The parties agree that individual depositions of inventors Jane C. Hirsh, Alison B. Fleming, Roman V. Rariy, and Alexander M. Klibanov shall be limited to a maximum of fourteen (14) hours per witness and that all other individual inventor and fact depositions shall be limited to a maximum of seven (7) hours per witness, unless otherwise agreed by the parties or by order of Court.

ii. Location of Depositions. The parties shall meet and confer regarding the locations of depositions, taking into account convenience for the deponent. Any party or representative (officer, director, or managing agent) of a party filing a civil action in this district court must ordinarily be required, upon request, to submit to a deposition at a place designated within this district. Exceptions to this general rule may be made by order of the Court or by agreement between the parties. A defendant who becomes a counterclaimant, cross-

claimant, or third-party plaintiff shall be considered as having filed an action in this Court for the purpose of this provision.

j. Disclosure of Expert Testimony.

i. Expert Reports. For the party who has the initial burden of proof on the subject matter, the initial Federal Rule 26(a)(2) disclosure of expert testimony is due on or before September 20, 2019. The supplemental disclosure to contradict or rebut evidence on the same matter identified by another party, which shall include expert reports to be submitted by Plaintiff regarding any objective indicia of non-obviousness, is due on or before November 1, 2019. Reply expert reports from the party with the initial burden are due on or before November 29, 2019. No other expert reports will be permitted without either the consent of all parties or leave of the Court. Along with the submissions of the expert reports, the parties shall advise of the dates and times of their experts' availability for deposition.

ii. Expert Depositions. All expert depositions shall be completed on or before January 31, 2020. Each side is limited to 7 hours of deposition time per expert, unless otherwise agreed by the parties or by order of Court. The parties agree that the 7 hour limitation may be expanded as appropriate for an expert offered on multiple issues (e.g. infringement and invalidity).

iii. Expert Report Supplementation. The parties agree they will permit expert declarations to be filed in connection with motions briefing and claim construction briefing.

iv. Objections to Expert Testimony. To the extent any objection to expert testimony is made pursuant to the principles announced in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), as incorporated in Federal Rule of Evidence 702, it shall be

made by motion no later than February 7, 2020, unless otherwise ordered by the Court.

Opposition briefs shall be due February 14, 2020. The parties agree to forego filing reply briefs.

Briefing on such motions is subject to the page limits set out in Local Rule 7.1.3(4).

k. Discovery Matters and Disputes Relating to Protective Orders.

i. Any discovery motion filed without first complying with the following procedures will be denied without prejudice to renew pursuant to these procedures.

ii. Should counsel find, after good faith efforts – including *verbal* communication among Delaware and Lead Counsel for all parties to the dispute – that they are unable to resolve a discovery matter or a dispute relating to a protective order, the parties involved in the discovery matter or protective order dispute shall submit a joint letter in substantially the following form:

Dear Judge Stark:

The parties in the above-referenced matter write to request the scheduling of a discovery teleconference.

The following attorneys, including at least one Delaware Counsel and at least one Lead Counsel per party, participated in a verbal meet-and-confer (in person and/or by telephone) on the following date(s):

Delaware Counsel: _____

Lead Counsel: _____

The disputes requiring judicial attention are listed below:

[provide here a non-argumentative list of disputes requiring judicial attention]

iii. On a date to be set by separate order, generally not less than forty-eight (48) hours prior to the conference, the party seeking relief shall file with the Court a letter, not to exceed three (3) pages, outlining the issues in dispute and its position on those issues. On a

date to be set by separate order, but generally not less than twenty-four (24) hours prior to the conference, any party opposing the application for relief may file a letter, not to exceed three (3) pages, outlining that party's reasons for its opposition.

iv. Each party shall submit two (2) courtesy copies of its discovery letter and any attachments.

v. Should the Court find further briefing necessary upon conclusion of the telephone conference, the Court will order it. Alternatively, the Court may choose to resolve the dispute prior to the telephone conference and will, in that event, cancel the conference.

8. Motions to Amend.

a. Any motion to amend (including a motion for leave to amend) a pleading shall *NOT* be accompanied by an opening brief but shall, instead, be accompanied by a letter, not to exceed three (3) pages, describing the basis for the requested relief, and shall attach the proposed amended pleading as well as a "blackline" comparison to the prior pleading.

b. Within seven (7) days after the filing of a motion in compliance with this Order, any party opposing such a motion shall file a responsive letter, not to exceed five (5) pages.

c. Within three (3) days thereafter, the moving party may file a reply letter, not to exceed two (2) pages, and, by this same date, the parties shall file a letter requesting a teleconference to address the motion to amend.

9. Motions to Strike.

a. Any motion to strike any pleading or other document shall *NOT* be accompanied by an opening brief but shall, instead, be accompanied by a letter, not to exceed

three (3) pages, describing the basis for the requested relief, and shall attach the document to be stricken.

b. Within seven (7) days after the filing of a motion in compliance with this Order, any party opposing such a motion shall file a responsive letter, not to exceed five (5) pages.

c. Within three (3) days thereafter, the moving party may file a reply letter, not to exceed two (2) pages, and, by this same date, the parties shall file a letter requesting a teleconference to address the motion to strike.

10. Tutorial Describing the Technology and Matters in Issue. Unless otherwise ordered by the Court, the parties shall provide the Court, no later than the date on which their opening claim construction briefs are due, a tutorial on the technology at issue. In that regard, the parties may separately or jointly submit a DVD of not more than thirty (30) minutes. The tutorial should focus on the technology in issue and should not be used for argument. The parties may choose to file their tutorial(s) under seal, subject to any protective order in effect. Each party may comment, in writing (in no more than five (5) pages) on the opposing party's tutorial. Any such comment shall be filed no later than the date on which the answering claim construction briefs are due. As to the format selected, the parties should confirm the Court's technical abilities to access the information contained in the tutorial (currently best are "mpeg" or "quicktime").

11. Claim Construction Issue Identification. On December 14, 2018, the parties shall exchange a list of those claim term(s)/phrase(s) that they believe need construction. On December 21, 2018, the parties shall exchange their proposed claim construction of those term(s)/phrase(s). These documents will not be filed with the Court. Subsequent to exchanging that list, the parties will meet and confer to prepare a Joint Claim Construction Chart to be

submitted on January 18, 2019. The parties' Joint Claim Construction Chart should identify for the Court the term(s)/phrase(s) of the claim(s) in issue, and should include each party's proposed construction of the disputed claim language with citation(s) only to the intrinsic evidence in support of their respective proposed constructions. A copy of the patent(s) in issue as well as those portions of the intrinsic record relied upon shall be submitted with this Joint Claim Construction Chart. In this joint submission, the parties shall not provide argument.

12. Claim Construction Briefing. The parties shall contemporaneously submit initial briefs on claim construction issues on February 22, 2019. The parties' answering/responsive briefs shall be contemporaneously submitted on March 22, 2019. No reply briefs or supplemental papers on claim construction shall be submitted without leave of the Court. Local Rule 7.1.3(4) shall control the page limitations for initial (opening) and responsive (answering) briefs.

13. Hearing on Claim Construction. Beginning at 1:00 p.m. on April 5, 2019, the Court will hear argument on claim construction. The parties shall notify the Court, by joint letter submission, no later than the date on which their answering claim construction briefs are due: (i) whether they request leave to present testimony at the hearing; and (ii) the amount of time they are requesting be allocated to them for the hearing. Provided that the parties comply with all portions of this Scheduling Order, and any other orders of the Court, the parties should anticipate that the Court will issue its claim construction order within sixty (60) days of the conclusion of the claim construction hearing. If the Court is unable to meet this goal, it will advise the parties no later than sixty (60) days after the conclusion of the claim construction hearing.

14. Interim Status Report. On April 29, 2019, counsel shall submit a joint letter to the Court with an interim report on the nature of the matters in issue and the progress of discovery to date. Thereafter, if the Court deems it necessary, it will schedule a status conference.

15. Supplementation. Absent agreement among the parties, and approval of the Court, no later than October 4, 2019 the parties must finally supplement, *inter alia*, the identification of all accused products and of all invalidity references (excluding any additional references to be relied on to rebut any objective indicia of non-obviousness raised by Plaintiff).

16. Case Dispositive Motions. Case dispositive motions will not be permitted.

17. Applications by Motion. Except as otherwise specified herein, any application to the Court shall be by written motion filed with the Clerk. Any non-dispositive motion should contain the statement required by Local Rule 7.1.1.

18. Pretrial Conference. On February 28, 2020, the Court will hold a pretrial conference in Court with counsel beginning at 9:00 a.m. Unless otherwise ordered by the Court, the parties should assume that filing the pretrial order satisfies the pretrial disclosure requirement of Federal Rule of Civil Procedure 26(a)(3). The parties shall file with the Court the joint proposed final pretrial order with the information required by the form of Revised Final Pretrial Order - Patent, which can be found on the Court's website (www.ded.uscourts.gov), on or before February 21, 2020. Unless otherwise ordered by the Court, the parties shall comply with the timeframes set forth in Local Rule 16.3(d)(1)-(3) for the preparation of the joint proposed final pretrial order.

The parties shall provide the Court two (2) courtesy copies of the joint proposed final pretrial order and all attachments.

As noted in the Revised Final Pretrial Order - Patent, the parties shall include in their joint proposed final pretrial order, among other things:

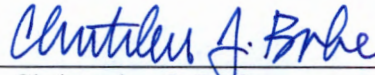
- a. a request for a specific number of **hours** for their trial presentations, as well as a requested number of days, based on the assumption that in a typical bench trial day there will be 6 to 7 hours of trial time;
- b. their position as to whether the Court should allow objections to efforts to impeach a witness with prior testimony, including objections based on lack of completeness and/or lack of inconsistency;
- c. their position as to whether the Court should rule at trial on objections to expert testimony as beyond the scope of prior expert disclosures, taking time from the parties' trial presentation to argue and decide such objections, or defer ruling on all such objections unless renewed in writing following trial, subject to the proviso that a party prevailing on such a post-trial objection will be entitled to have all of its costs associated with a new trial paid for by the party that elicited the improper expert testimony at the earlier trial; and
- d. their position as to how to make motions for judgment as a matter of law, whether it be immediately at the appropriate point during trial or at a subsequent break and whether such motions may be supplemented in writing.

19. Motions in Limine. Motions *in limine* shall not be separately filed. All *in limine* requests and responses thereto shall be set forth in the proposed pretrial order. Each **SIDE** shall be limited to three (3) *in limine* requests, unless otherwise permitted by the Court. The *in limine* request and any response shall contain the authorities relied upon; each *in limine* request may be supported by a maximum of three (3) pages of argument and may be opposed by a maximum of three (3) pages of argument, and the side making the *in limine* request may add a maximum of one (1) additional page in reply in support of its request. If more than one party is supporting or opposing an *in limine* request, such support or opposition shall be combined in a single three (3)

page submission (and, if the moving party, a single one (1) page reply), unless otherwise ordered by the Court. No separate briefing shall be submitted on *in limine* requests, unless otherwise permitted by the Court.

20. Trial. This matter is scheduled for a five (5) day bench trial beginning at 9:30 a.m. on March 9, 2020, with the subsequent trial days also beginning at 9:30 a.m. The trial day will end no later than 5:00 p.m. each day.

21. Post-Trial Briefing. The parties will address the post-trial briefing schedule and page limits in the proposed final pretrial order.



Hon. Christopher J. Burke
United States Magistrate Judge